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PATENT  
Docket No. 275.0009 0101IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): MUNN et al. ) Group Art Unit: 1614  
Serial No.: 10/780,150 ) Examiner: Charlesworth E. Rae  
Confirmation No.: 1273 )  
Filed: February 17, 2004 )  
For: REGULATION OF T CELL-MEDIATED IMMUNITY BY D ISOMERS OF  
INHIBITORS OF INDOLEAMINE-2,3-DIOXYGENASE

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Commissioner for Patents  
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1. RESPONSE TO RESTRICTION REQUIREMENT (4 PGS)
2. PRELIMINARY AMENDMENT (5 PGS)
3. SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (2 PGS)
4. 1449 FORM (1 PG)
5. COPY OF ONE DOCUMENT CITED ON 1449 FORM (65 PGS)

X Small Entity Status is entitled to be asserted in the above-identified application.

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers and please charge any additional fees or credit overpayment to Deposit Account No. 13-4895.

Mueiting, Raasch & Gebhardt, P.A.  
Customer Number: 26813

December 19, 2006  
Date

By: Nancy A. Johnson  
Nancy A. Johnson  
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December 19, 2006  
Date

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Name: Sandy Truehart

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**RESPONSE TO RESTRICTION REQUIREMENT**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

In response to the Restriction Requirement mailed November 21, 2006, Applicants elect, with traverse, Group IX (claim 42), drawn to a method of delaying the relapse or progression of a tumor in a subject, the method comprising administering an effective amount of a pharmaceutical composition comprising a D isomer of an inhibitor of indoleamine-2,3-dioxygenase (IDO). Applicants submit that claims 2, 3, 6-10, and 17-26, in view of the Preliminary Amendment filed herewith, properly belong in Group IX. Applicants' Representatives reserve the right to pursue examination of the non-elected claims in continuation or divisional applications. Applicants respectfully request reconsideration of the restrictions in this case and submit that the inventions as claimed can be readily evaluated in one search without placing undue burden on the Examiner.

Applicants request the rejoinder of Groups I, II, IX, and X. Applicants submit that the burden to search and examine the methods of Groups I, II, XI, and X, all drawn to methods comprising the administration of a pharmaceutical composition comprising an inhibitor of IDO, is not unduly burdensome. Reconsideration and examination of the claims of Groups I, II, and X along with the claims of IX is respectfully requested.

**Response to Restriction Requirement**

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The claimed invention is drawn to methods comprising the administration of a D isomer of an inhibitor of IDO. Thus, Applicants do not understand the Examiner's classification of the claimed invention in, for example, class 514, subclasses 69.2, 109, 263.1, 283, and 419 (see elected Group IX, claim 42) or subclass 6 (see, for example, Group X, claim 43). A subclass 69.2 does not seem to exist in class 514. According to the classification manual, class 514, subclass 6 is drawn to the administration of a peptide containing (e.g., protein, peptones, fibrinogen, etc.) designated organic active ingredient (DOAI) containing a heavy metal (e.g., hemoglobin, etc.). Applicants do not understand the relationship of class 514, subclass 6 to the invention of claim 43. According to the classification manual, class 514, subclass 109 is drawn to the administration of a DOAI wherein the organic active ingredient contains a phosphorus atom, in which the organo-phosphorus compound has a single phosphorus atom linked directly to a chalcogen atom which in turn is linked directly to another chalcogen atom. Again, Applicants do not understand the classification of the invention of claim 42 in class 514, subclass 109. For similar reasons, Applicants do not understand the inclusion of the invention of claim 42 in class 514, subclasses 263.1, 283, and 419. Applicants respectfully submit that the Examiner's classification of the present invention is incorrect. Given that the Examiner's classification of the claimed invention is used to justify the instant Restriction Requirement, and that this classification appears to be incorrect, reconsideration and withdrawal of the Restriction Requirement is requested.

In regard to the Election of Species requirements, Applicants elect, with traverse:

- a1) 1-methyl-D-tryptophan;
- A) claim embodiments comprising administration of a pharmaceutical composition comprising an inhibitor of IDO;
  - a) administration of one or more chemotherapeutic agents; and
  - a1) melanoma tumor cells.

## Response to Restriction Requirement

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With respect to these species elections, these elections are with traverse to the extent that it is understood that (a) the requirement will be withdrawn upon the finding of an allowable genus; and (b) any species withdrawn from consideration will be transferred to the elected subject matter unless it is found patentably distinct from the elected or allowed claims. Applicants traverse on the grounds that the generic claim includes sufficiently few species that a search and examination of all the species at one time would not impose a serious burden on the Examiner.

With respect to the Examiner's requirement that Applicants elect from "A) Claim embodiments with a D-isomer of an inhibitor of indoleamine-2,3-dioxygenase *alone*, [and] B) Claim embodiments with said D-isomer in combination with other therapeutic modalities" (page 6-7, Office Action mailed November 21, 2006 (emphasis added)), Applicants submit that this election of species requirement between A and B is improper. First, Applicants submit that the Examiner is improperly characterizing and unduly limiting the Applicants' claimed invention. Independent claims 1, 27, 42, and 43 are drawn to a "method . . . *comprising* administering . . . a pharmaceutical composition *comprising* a D-isomer of an inhibitor of indoleamine-2,3-dioxygenase." Claims 1, 27, 42, and 43 utilize open language "*comprising*". Thus, the Examiner's assertion that claims 1, 27, 42, and 43 are drawn to the administration of a D-isomer of an inhibitor of IDO *alone* is incorrect. Further, claims 6-10 and 17-26 depend from independent claims 1, 27, 42, or 43. Applicants submit that independent claims 1, 27, 42, and 43 (Examiner's species A) are generic to dependent claims 6-10 and 17-26 (Examiner's species B) and an election of species between, for example, independent claim 42 and dependent claims 6-10 and 17-26 is improper. Reconsideration and withdrawal of the election of species requirement between Species A and B is respectfully requested.

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The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if there are any questions regarding this Response or if prosecution of this application may be assisted thereby.

**CERTIFICATE UNDER 37 C.F.R. 1.8:**

The undersigned hereby certifies that this paper is being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

on this 19 day of Dec., 2006, at  
11:25 A.M. (Central Time).

Sandy Truehart  
Name: Sandy Truehart

Respectfully submitted

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